Collection of Data on Specialized Cardiac Care Services: Percutaneous Coronary Intervention Services (Primary and Non-Primary) and Cardiac Surgery Services

PCI Data Work Group

December 7, 2009

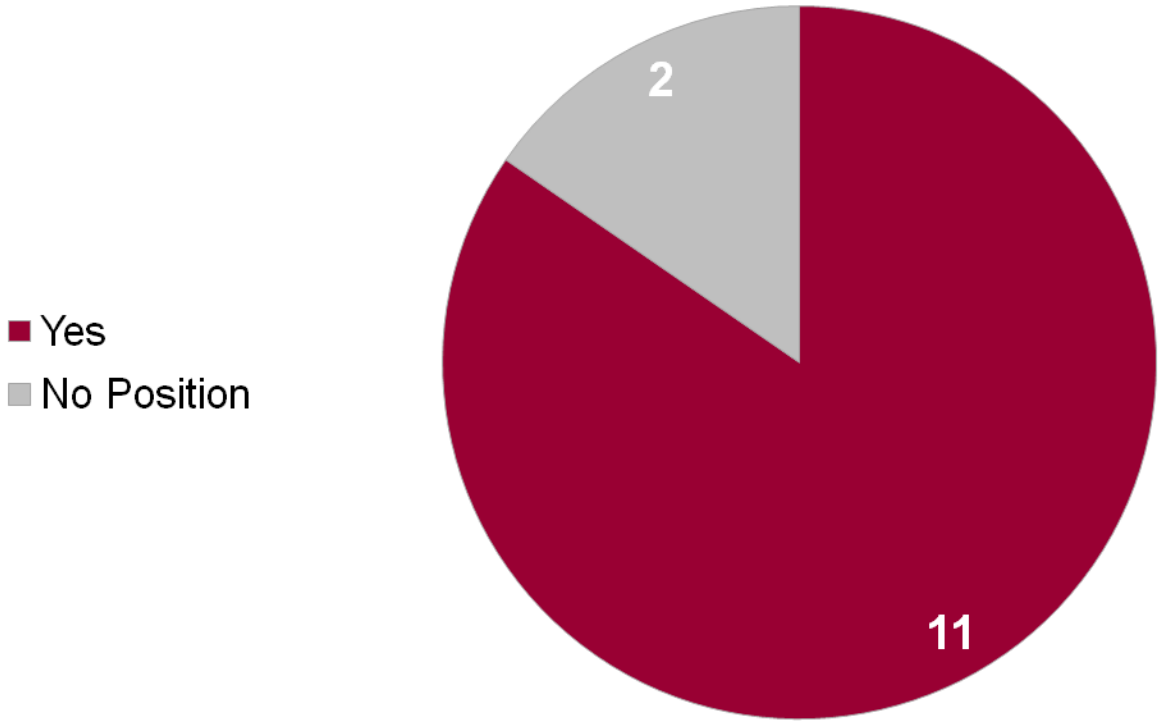
Organizations Submitting Comments During the Public Comment Period

- Adventist HealthCare
- American College of Cardiology (Maryland Chapter)
- American Heart Association
- Anne Arundel Medical Center
- Carroll Hospital Center
- Frederick Memorial Healthcare System
- Holy Cross Hospital
- Johns Hopkins Health System
- MedStar Health
- Maryland Institute for Emergency Medical Services Systems (MIEMSS)
- Peninsula Regional Medical Center
- Southern Maryland Hospital Center
- Society for Cardiovascular Angiography and Interventions
- University of Maryland Medical Center
- Western Maryland Health System

Should the Commission establish a Maryland STEMI Data Base to include all hospitals providing pPCI Services?

Maryland STEMI Data Base

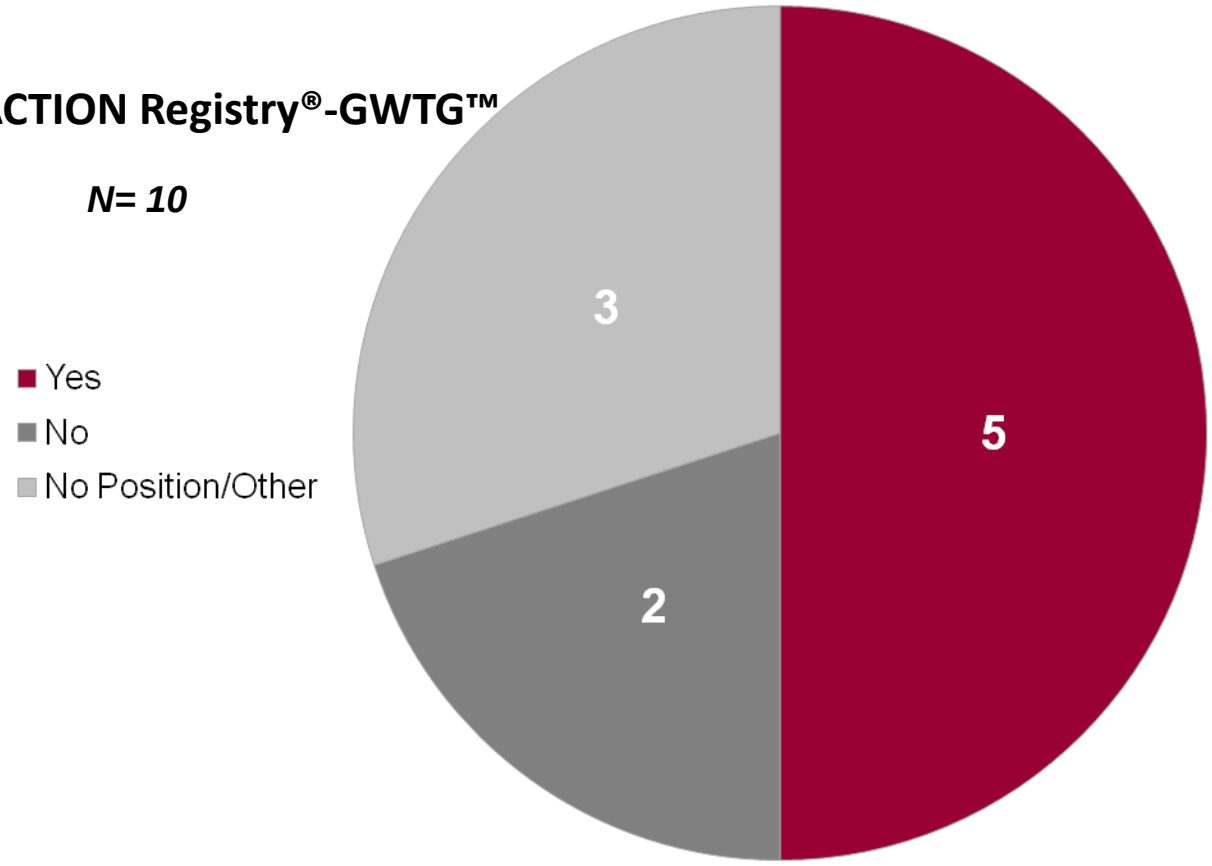
N= 13



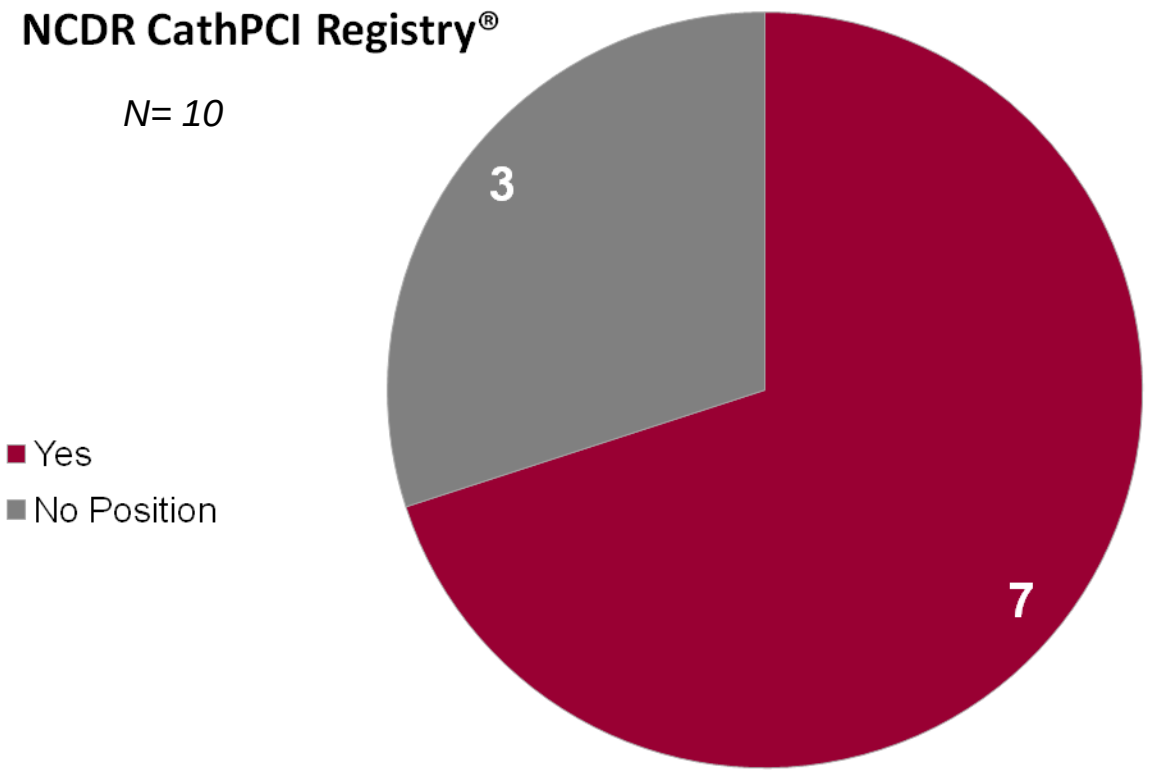
Should the ACTION Registry®-GWTG™ be adopted as the standard data set required for all Maryland pPCI patients?

ACTION Registry®-GWTG™

N= 10



Should the Commission adopt the NCDR CathPCI Registry® data base for PCI services?



Comments Received by Topic

- Comments on ACTION
- Comments on NCDR CathPCI
- Unintended Consequences of Public Reporting
- Importance of Risk Adjustment
- Data Uses
- Data Collection Format and Timetable
- Funding for Data Collection
- Data Validation
- Inclusion of Hospitals in the PCI Data Base and Related Issues

Issues Raised in Public Comments: Comments on the ACTION Registry

Public Comments

- ACTION Registry falls short on a series of criteria, most notably its risk-adjustment paradigm. ….ACTION registry also does not adequately collect follow-up data on patients.

- ACTION Registry-GWTG also provides the opportunity to see how the full system of care is performing. The program allows tracking from first medical contact with EMS to care received at/between multiple hospitals, should the patient need to be transferred from a non-PCI-capable facility to one that has primary PCI-capabilities.

- ACTION Registry-GWTG functions as the primary data tool for the AHA's Mission: Lifeline program.

- MIEMSS selected Get with the Guidelines–Stroke (GWTG–Stroke) as the quality improvement tool for all primary stroke centers in Maryland. To date, 35 Maryland hospitals are using GWTG–Stroke and submitting data to MIEMSS for continuous quality improvement, which is facilitated through the Stroke QIC (Quality Improvement Committee)….. Over 16 hospitals in Maryland have been recognized with GWTG–Stroke achievement awards, based on their improved performance in meeting guidelines.

- ACTION Registry®-GWTG™ is a comprehensive data set for hospitals that provide pPCI services…. With the addition of the pre-hospital data elements, the ACTION Registry®-GWTG™ would be an ideal standard data set for use by Maryland hospitals providing pPCI.

Issues Raised in Public Comments: Comments on the ACTION Registry

Public Comments (Continued)

- The ACTION Registry®-GWTG™ includes up to eight or ten extra fields which could potentially be customized to include additional data. The ACTION Registry®-GWTG™ also appears to be more focused on quality improvement initiatives and appears to offer more flexibility and adaptability than other databases.

- ACTION Registry®-GWTG™ is a relatively new and untested registry that is designed for use in all hospitals that treat patients with acute myocardial infarctions (MIs)….. since the registry is funded by pharmaceutical manufacturers, exempting hospitals that only provide medical therapy to acute MI patients does not seem appropriate.

Issues Raised in Public Comments: Comments on the NCDR CathPCI Registry

Public Comments

- NCDR CathPCI Registry, which is more widely used, can provide the appropriate data, thereby minimizing an additional administrative burden to the hospitals and the State.

- The NCDR CathPCI Registry includes a PCI in-hospital, risk-adjusted mortality model that has the National Quality Forum endorsement as part of quarterly benchmark reports, and will be expanding to risk-adjustment metrics for vascular complications and major bleeding events in 2010.

Issues Raised in Public Comments: Unintended Consequences of Public Reporting

Public Comments

- Effect of public outcomes reporting on the treatment of high risk patients

- Steps should be taken to ensure that unintended consequences are not the result of publicly reporting data. Publicly reported data should identify only observed differences that are statistically significant.

Issues Raised in Public Comments: Need for Risk Adjustment

Public Comments

- Recognition of the importance of appropriate risk stratification factors
- Appropriate use of statistical methods for risk adjustment
- Patients seen at hospitals with cardiac surgery have a higher acuity mix and may look very different from patients currently cared for by community hospitals without cardiac surgery programs. Therefore, the small volume of STEMI patients admitted via the ED reported at these facilities may not be a fair comparison with high volume community hospitals in the Maryland STEMI database.
- Any reporting of institution specific patient clinical outcomes should be meticulously risk-adjusted and adjudicated. All stakeholders should be given the opportunity to work with the MHCC to minimize unintended negative consequences from public reporting due to incomplete risk-adjustment or the reporting of non-statistically significant differences.
- Public release may not provide a comprehensive risk-adjustment methodology and a sophisticated, but easily understandable presentation of the statistical significance of any observed differences.

Issues Raised in Public Comments: Need for Risk Adjustment

Public Comments (Continued)

- Statistical significance at the physician level is even more difficult to obtain and should probably not even be attempted until valid data are available at the facility level.

- The NCDR risk adjustment methodology does not include many important details and adverse outcomes are not adjudicated to ensure that they were related to the performance of the facility, physician or staff. The model in Massachusetts works with data developed through the NCDR process and with the affected hospitals to improve data accuracy and adjudicate the reasons for adverse events in these registries before releasing the data to the public. The adjudication process works to ensure that only adverse events are not random occurrences but related to the quality of care that was delivered to those patients.

Issues Raised in Public Comments: Data Uses

Public Comments

- Need to clarify multiple uses of the data (regulatory decisions, planning, and outcomes reporting)
- Special considerations regarding the availability of the data to hospitals and the public
- Concern about how information from the CathPCI registry would be used if it were to be adopted for all hospitals performing PCI. Results gathered from the Maryland STEMI Registry are used to enforce the standards for delivery of primary PCI services described in COMAR 10.24.17, but only for hospitals with a waiver that allows them to perform pPCI. Adoption of a single data base and reporting for all hospitals would newly allow external monitoring of primary PCI process and outcome measures for hospitals with cardiac surgery on-site.
- Data collected in Maryland STEMI database is tracked at its institution as part of the AMI core measure and door-to-balloon-time. PRMC added that the data are readily available as part of the hospital core measures reporting.

Issues Raised in Public Comments: Data Collection Format and Timetable

Public Comments

- Additional questions that need to be considered concern whether the MHCC plans to collect the ACC-NCDR quarterly reports or to collect the raw data. Clearly, collecting the raw data provides a more powerful analytical tool at the State- level.
- Inclusion of sunset provisions given the time-limited nature of the waivers
- Timeframe for implementation of new systems
- Release of NCDR CathPCI data registry scores would not be in the best interest of patients in Maryland.
- MHCC should refine the new door-to-balloon time requirements in COMAR 10.24.17.
- The State should evaluate measures of “all cause mortality versus cardiac mortality”.

Issues Raised in Public Comments: Funding for Data Collection

Public Comments

- Need for adequate additional funding to the participating institutions to cover any additional cost burden of data collection.

- Participating in registries requires significant fees from the facilities and even greater costs for data collection and reporting.

- The data collection process is very labor intensive. Data duplication is a significant concern for those individuals abstracting the data and increases the need for added personnel to collect and submit different standards/measures. The ability to collect and distribute all of the data to one repository allows the measures to then be distributed to the various organizations requiring the data. Additionally, the data is consistent, accurate and based on the same data definitions. This enhances patient outcomes by assuring accuracy in data interpretation and application of the same standards of care to all who are providing the service.

Issues Raised in Public Comments: Data Validation

Public Comments

- Currently, the SEXTANT database requires the submission of documents to validate various key elements, including documents that provide the patient's arrival and balloon time. The existing process includes an audit and validation process. A similar process should be implemented in conjunction with the designation of a new registry database.

- ACTION Registry ®-GWTG™ may not be robust enough to meet the Commission's need for data quality, as it does not include a mechanism for independently checking and validating the data entered by individual sites into the registry.

- The ACTION Registry®-GWTG™ does not have a well-defined validation process to ensure that all elements are submitted accurately.

- MHCC consider the development of an education and credentialing process on data reporting and the development of a monitoring and audit function to assure data integrity.

Issues Raised in Public Comments: Data Validation

Comments (continued)

- NCDR registries require hospitals to submit data on 100 percent of patients that meet the inclusion criteria. By receiving data directly from the NCDR, the MHCC can take advantage of the NCDR's data validation process that automatically reviews quarterly data submissions for completeness before accepting data for aggregation, and provides hospitals with immediate feedback regarding incomplete submissions.

- The data in the CathPCI registry undergoes only minimal auditing.

- The State should include in regulation for PCI data reporting provision for periodic external data audits, with on-site comparison of submitted data with source material; and, support audits with adequate ongoing funding.

Issues Raised in Public Comments: Inclusion of Hospitals in PCI Data Base and Related Issues

Public Comments

- There are concerns that the volume of cases participants are performing may hamper meaningful results. This is particularly true in the case of hospitals which are operating on waivers, such as with respect to the C-PORT-E trial. The randomization process in this research study of non-primary PCI hampers the facility's volume. Without a significant volume, the statistical analysis will not carry enough merit to make substantive conclusions about how that hospital performs. Quarterly reports on this data could result in misinterpretation.

- Statewide reporting outside of C-PORT-E is not necessary due to the sensitive clinical and political nature of the npPCI service…. the decision of State reporting of npPCI services should be made at the conclusion of the C-PORT-E trial.

- Provisions for out-of-state hospitals to participate in the registry, in anticipation of being designated as a STEMI referral center

- MHCC should establish a minimum threshold for the number of STEMI patients cared for at the hospital to be considered for inclusion in the database. Although most of the hospitals that perform cardiac surgery see large volumes of STEMI patients transferred from outside hospitals, only those STEMI patients admitted from their Emergency Departments are publicly reported.

Background Information

Maryland Hospitals Currently Enrolled in the Maryland STEMI Registry, NCDR™ ACTION Registry® – GWTG™ and NCDR® CathPCI Registry®

Hospital	NCDR™ ACTION - GWTG	NCDR® CathPCI	Maryland STEMI Registry
Waiver Hospitals (without on-site cardiac surgery)			
Anne Arundel Medical Center	X		X
Baltimore Washington Medical Center	X		X
Carroll Hospital Center	X	X	X
Franklin Square Hospital Center			X
Frederick Memorial Hospital		X	X
Holy Cross Hospital	X		X
Howard County General Hospital		X	X
Johns Hopkins Bayview Medical Center		X	X
Saint Agnes Hospital	X		X
Shady Grove Adventist Hospital	X	X	X
Southern Maryland Hospital Center	X	X	X
Upper Chesapeake Medical Center		X	X
Washington County Hospital		X	X
Cardiac Surgery Hospitals			
Braddock Hospital	X	X	
Johns Hopkins Hospital		X	
Peninsula Regional Medical Center		X	
Prince George's Hospital Center		X	
St. Joseph Medical Center		X	
Sinai Hospital		X	
Suburban Hospital		X	
Union Memorial Hospital		X	
University of Maryland Medical Center		X	
Washington Adventist Hospital	X	X	
Other Hospitals			
Garrett County Memorial Hospital	X		
Montgomery General Hospital	X		